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Randomised controlled clinical trial of oral etoposide versus intravenous multi-drug chemotherapy in the palliative treatment of patients with Small-Cell Lung Cancer (SCLC) and a poor prognosis

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 15/11/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LU16

Study information

Scientific Title
Randomised controlled clinical trial of oral etoposide versus intravenous multi-drug chemotherapy in the palliative treatment of patients with Small-Cell Lung Cancer (SCLC) and a poor prognosis

Study objectives
Not provided at time of registration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Small-Cell Lung Cancer (SCLC)

Interventions
1. Oral Etoposide Regimen (E): Four courses of oral etopsimide twice daily for ten days at three week intervals (i.e. ten days of chemotherapy in each three week period).

2. Intravenous Multi-Drug
Chemotherapy Regimen (EV or CAV): Clinicians chose to use one of two multi-drug chemotherapy regimens: EV: Intravenous etoposide and vincristine four courses given at three

week intervals, each course given over three days according to the protocol.
CAV: Intravenous cyclophosphamide, doxorubicin and vincristine four courses given at three week intervals, each course given on one day.

All treatments should start as soon as possible after randomisation.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Etopsimide, cyclophosphamide, doxorubicin and vincristine

Primary outcome measure
Not provided at time of registration.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/08/2002

Completion date
01/08/2003

Eligibility

Key inclusion criteria
1. Microscopically proven SCLC
2. Limited or extensive disease
3. World Health Organisation (WHO) performance status grade two, three or four
4. No previous chemotherapy, radiotherapy, or surgery for small-cell lung cancer
5. No other previous or concomitant malignant disease, except basal cell carcinoma or in situ carcinoma of the cervix
6. No other serious condition contraindicating treatment with cytotoxic chemotherapy. Patients with evidence of liver cell damage are eligible
7. Renal function normal: plasma creatinine or urea concentration within normal limits
8. Plasma Billirubin less than 35 µmol/l
9. Any age, either sex

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration.

Total final enrolment
339

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/08/2002

Date of final enrolment
01/08/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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Sponsor type
Research council

Website

http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/08/1996	15/11/2019	Yes	No